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No. 85-664

IN THE

Supreme Court of the United States

OCTOBER TERM, 1985

FRANK YOUNG, Commissioner of Food and Drugs,
Petitioner,

v.

COMMUNITY NUTRITION INSTITUTE, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

BRIEF OF SOUTH CAROLINA AS *AMICUS CURIAE* IN SUPPORT OF PETITION FOR WRIT OF CERTIORARI

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STATEMENT OF INTEREST OF THE AMICUS CURIAE

In 1980, South Carolina, together with its sister states of North Carolina and Virginia, petitioned the Food and Drug Administration (FDA) for a temporary amendment of FDA's "action level"[1] for corn

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[1] FDA "action levels" are maximum permissible levels for unavoidable substances in food. FDA uses these levels for determining whether the food "may be injurious to health" and for recommending regulatory action under § 402(a)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA or Act), 21 U.S.C. § 342(a)(1).

bearing small quantities of aflatoxin, a mold by-product which develops in corn in the field.

In some years, because of unusually wet or unusually dry weather conditions, the level of aflatoxin in the corn crop may exceed the 20 parts per billion (ppb) action level established in 1974 by FDA. 39 *Fed. Reg.* 42748 (December 6, 1974). When such circumstances occurred in 1980, South Carolina had to choose between either obtaining the FDA's cooperation in regulating the interstate use of corn with aflatoxin above 20 ppb or regulating the use and disposition of such corn solely within the borders of South Carolina. South Carolina chose the first course by petitioning FDA to raise the aflatoxin action level to 100 ppb for certain safe, animal feed uses of the corn in non-lactating and mature livestock and poultry, while leaving the 20 ppb action level in effect for aflatoxin on corn used as human food or as feed to dairy cattle.

South Carolina has appeared as *amicus curiae* on behalf of the Commissioner of Food and Drugs during both the United States District Court and the United States Court of Appeals proceedings.

The State of South Carolina is vitally concerned with its ability to obtain revised federal regulatory guidelines to properly regulate the temporary occurrence of a contaminant in the food supply. Thus, South Carolina sees great need and importance for FDA to be able to respond flexibly and promptly by issuing, in the *Federal Register*, a revised action level expressing FDA's view as to whether a product is adulterated under § 402(a)(1) of the FDC, 21 U.S.C. § 342(a)(1). The Court of Appeals' apparent requirement on FDA to issue a tolerance using the formal trial type

rulemaking procedures of § 701(e) of the FDCA pursuant to §§ 402(a)(2)(A) & § 406 of the Act, 21 U.S.C. §§ 342(a)(2)(A) & 346, would hamstring State and Federal regulatory bodies in directing safe uses of food unavoidably containing environmental contaminants.

1. Statement of Facts

For a number of years, FDA has maintained an action level for aflatoxin in corn at 20 ppb. An action level simply expresses FDA's policy as to the level at which the Agency considers a food to be adulterated. FDA has established action levels for a variety of food defects and contaminants including insect parts in imported spices and traces of pesticides in non-target crops. Prior to 1972, FDA refused to divulge these policy guidelines, but since that time FDA has made this information publicly available to give guidance to industry and state officials. 37 *Fed. Reg.* 6497 (March 30, 1972).

In 1980, the corn crop in the southeastern portion of the United States contained a higher than usual level of aflatoxin due to an unusual combination of early drought and late rains. Therefore, South Carolina together with North Carolina and Virginia requested FDA reconsider its enforcement policies towards such corn. The three States submitted that since corn with elevated levels of aflatoxin (100 ppb) can be safely used as feed for non-lactating animals and poultry, FDA should rule that corn with aflatoxin up to 100 ppb would not be adulterated when limited to such use while leaving intact the action level of 20 ppb for all other uses. FDA agreed. 46 *Fed. Reg.* 7447

(January 23, 1981). The Community Nutrition Institute then filed the present action in the United States District Court for the District of Columbia questioning FDA's authority to change its enforcement intentions regarding corn bearing aflatoxin without resorting to formal, trial type rulemaking pursuant to §§ 406 and 701(e) of the FDCA, 21 U.S.C. §§ 346 & 371(e).

2. Proceedings Below

The United States District Court for the District of Columbia heard the present case on cross motions for summary judgment and granted the motion filed by the FDA. The court correctly ruled that § 406 did not mandate tolerances for unavoidable poisonous or deleterious substances.

The United States Court of Appeals for the District of Columbia Circuit reversed, finding that FDA can only allow the shipment of products containing *any* food contaminant if it first promulgates a tolerance pursuant to §§ 406 and 701(e) of the Act. The Court of Appeals decision wrote § 402(a)(1) out of the FDCA and, in effect, overruled this Court's decisions in *Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153 (1958), and *United States* v. *Lexington Mill and Elevator,* 232 U.S. 399 (1914).

ARGUMENT

A. When A Food Contains An Unavoidable Poisonous or Deleterious Substance For Which No Tolerance Has Been Established, Section 406 Of The Federal Food, Drug and Cosmetic Act Does Not Apply

Section 406 of the Act was added as part of the 1938 revision of the 1906 Pure Food and Drug Act.

This section, by its plain language, addresses two specific and factual circumstances. The first clause of the first sentence provides that the addition of any *unnecessary or avoidable* poisonous or deleterious substance (in any amount) renders the product adulterated under § 402(a)(2)(a) of the Act.[2] The second clause of the first sentence states that if the substance is necessary for production or unavoidable *and* a tolerance is in effect, any product which contains such substances in excess of the tolerance is adulterated under § 402(a)(2)(a).[3]

The section does not expressly address the question of those situations when the substance is unavoidable *and* no tolerance has been established. However, the second sentence in Section 406 gives guidance on how the above question is to be answered. This sentence reads: "While such a [tolerance] is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated with the meaning of clause (1) of Section 342(a) of this title." Accordingly, the sentence explains that a 406 tolerance takes the food

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[2] The clause reads: "Any poisonous or deleterious substance added to any food, *except where such substance is required in the production thereof or cannot be avoided* by good manufacturing practices, shall be deemed to be unsafe for purposes of the application of clause (2)(A) of Section 342(a) of this title . . . ." (Emphasis added).

[3] This clause reads: "but when such substance is so required or cannot be so avoided the Secretary shall promulgate regulations limiting the quantity therein . . . and any quantity *exceeding* the limits so fixed shall be deemed to be unsafe for purposes of the application of clause (2)(A) of Section 342(a) of this title . . . ." (Emphasis added).

out of § 402(a)(1). In the absence of a tolerance, it follows that the food would remain subject to § 402(a)(1). Under this section a food is adulterated "if it bears or contains any poisonous or deleterious substance *which may render* it injurious to health. . . ." Section 402(a)(1) (emphasis added).

This conclusion is supported by this Court's opinion in *Flemming* v. *Florida Citrus Exchange*, 358 U.S. 153 (1958). There, this Court held that § 406 carved out specific exceptions to the general adulteration provision found in § 402(a)(1). "The existence of a tolerance is specifically stated in § 406(a) [currently 406] *only to give sanction to what would otherwise amount to adulteration within the terms of § 402(a)(1). Id.* at 166 (emphasis added). When § 406 does not apply, § 402(a)(1) will govern.[4] To hold § 406 covers *all* poisonous or deleterious substances would write § 402(a)(1) out of the statute entirely. Unfortunately, the Court of Appeals below did so hold.

B. The Court of Appeals Incorrectly Held A Food Containing *Any* Amount Of A Poisonous or Deleterious Substance Is Adulterated

The weakness of the Court of Appeals' reasoning is that it presumed any amount of a poisonous or deleterious substance rendered the food adulterated. Slip Op. at 7 (*Reprinted* in Petition For Writ of Certiorari at 7a). However, under § 402(a)(1) of the FDCA, as interpreted by this Court in *United States*

[4] Additionally, the legislative history makes clear that § 406 merely "authorizes," but not requires FDA to establish tolerances. See, S. Rept. No. 493, 73rd Cong., 2d Sess. 4 (1934).

v. *Lexington Mill & Elevator Co.*, 232 U.S. 399 (1914),[5] the mere presence of a poisonous or deleterious substance (if unavoidable) does *not* render a product adulterated; rather, the substance must be present in such a quantity which may render the product injurious to health. *Id.* at 410. Accordingly, in situations where the poisonous or deleterious substance is unavoidable and no tolerance has been established, the food is not adulterated unless the quantity is sufficient so that the product "may be injurious" to health. The mere presence of an unavoidable poisonous or deleterious substance alone does not render a product adulterated under the *Lexington Mill* opinion.

C. The Court of Appeals, By Ignoring § 402(a)(1) and the Supreme Court's Decision in *United States* v. *Lexington Mill & Elevator Co.*, Misconstrued FDA's Action In This Controversy

Contrary to the decision below, FDA did not authorize the shipment of adulterated product. FDA addressed the question of whether a certain level of aflatoxin (100 ppb) "may render" corn injurious to health, when used as feed for mature non-lactating cattle and poultry. In its determination that the product could be shipped, FDA did *not* state the product was adulterated but could be shipped nonetheless; FDA stated that it could not conclude that the 100 ppb level for those uses "may render" the product injuri-

[5] The *Lexington Mill* case involved § 7 of the Pure Food and Drugs Act of 1906 (34 Stat. 769) which was the predecessor provision to the current § 402(a)(1) of the FDCA. Yet, the *Lexington Mill* decision retained its applicability and vitality after the 1938 revision. *See, e.g., Flemming* v. *Florida Citrus Exchange*, 358 U.S. at 161 (1958).

ous to health under § 402(a)(1) of the Act. Therefore, the product is not adulterated. FDA simply recognized it lacked the scientific grounds and evidence to proceed against the product. Since FDA did not find the product to be adulterated, it was not mandated to establish a tolerance. *Cf. Flemming* v. *Florida Citrus Exchange,* 358 U.S. 153 (1958).

D. The Decision Unduly Hinders South Carolina In Its Regulatory Enforcement

Not only does the Court of Appeals decision rewrite the FDCA, it creates an enormous regulatory burden on South Carolina. South Carolina has the same interest as the federal government in protecting its citizens from products which contain poisonous or deleterious substances which may render the product injurious to health. However, this interest would not be served if the Court of Appeals holding—that all products which contain even a trace of poisonous or deleterious substances are adulterated unless FDA establishes formal tolerances—is allowed to stand.

First, since the decision only applies to products shipped in interstate commerce,[6] farmers would be prohibited from shipping in interstate commerce under the decision. This means the products would remain within the state. This would leave South Carolina with the entire regulatory responsibility and burden for ensuring the products are not used in ways which threaten the public health.

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[6] FDA's authority to regulate or prohibit the shipment of adulterated food is limited to either the interstate shipment of the product or movement of the components of the food product in interstate commerce. *See*, §§ 301(a) & (k) of the FDCA, 21 U.S.C. §§ 331(a) & (k).

Second, the Court of Appeals' decision would prohibit FDA from indicating what levels it feels constitute adulteration under § 402(a)(1)—this could be construed as an impermissible action level—and South Carolina would be denied FDA guidance on what levels and uses are safe. South Carolina does not have the resources of FDA in these matters, thus compromising the public health.

Third, the Court of Appeals' decision would deny South Carolina the opportunity to work with FDA to develop plans for the distribution of the product which, through an Act of God, contains unavoidable poisonous or deleterious substances but which do not threaten the public health.

The Court of Appeals felt such concerns could be answered if FDA simply established formal tolerances. In reality, such would not occur. Under 701(e) of the Act, 21 U.S.C. § 371(e), tolerances are subject to formal adjudicative rulemaking procedures, not simple notice and comment rulemaking. This procedure is extremely time-consuming. Indeed, on the simple question of whether peanut butter should contain 87% or 90% peanuts, the FDA formal rulemaking transcended ten years and accumulated over 32,000 pages of hearing transcript. *See* Hamilton, *Rulemaking on a Record by the Food and Drug Administration,* 50 Tex. L. Rev. 1132 (1972). Even if a tolerance was eventually established, FDA would lack the flexibility either to respond to a request for modification in light of unforeseen circumstances, such as the South Carolina 1980 request, or to tighten the tolerances in light of new data to better protect the public health. South Carolina should not be forced to wait ten years to obtain FDA guidance whether a particular use of a

perishable product violates § 402(a). Nor, should the public be exposed to ten years of unsafe levels of poisonous or deleterious substances where new scientific evidence simply demonstrates that a tolerance is outdated.

CONCLUSION

For the above reasons, the State of South Carolina respectfully requests this honorable Court grant the Petitioner's Request for a *Writ of Certiorari.*

Respectfully submitted,

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